



Answers to Your Questions: Outpatient Treatment with Interleukin-2 (IL-2)

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*Welcome to the Clinical Center at the National Institutes of Health. Your health care team prepared this information to give you as much information as possible about your immunotherapy treatment. * It will describe what immunotherapy is and what to expect from your treatment. It will also explain how you and your health care team will manage the common side effects of this therapy.*

There is a lot of information here, so we encourage you to read it one section at a time. You may refer to this information throughout your treatment.

If you have questions or concerns about your treatment, call a member of your immunotherapy team at any time. Their telephone numbers are included in this information.

Your immune system

Your body's first response to an invasion by viruses or bacteria is called an immune response. The immune response is like an alarm. It signals your body that an unfamiliar substance has entered, which does not belong there. The immune response is triggered by your immune system.

Your immune system protects you from foreign or unfamiliar substances by recognizing them as harmful. It is constantly alert for disease-causing organisms, viruses, bacteria, and fungi.

Your immune system can also recognize cancer cells. When this happens, the immune system

sends fighter cells (lymphocytes, a type of white blood cell) to destroy the unfamiliar substances invading your body.

Interleukin-2 (IL-2) is a protein made in small amounts by your body's lymphocytes. IL-2 activates your immune system to help your body fight cancer. To make large amounts of IL-2, scientists have put the gene for IL-2 into harmless bacteria. This is known as recombinant IL-2. Many studies have shown that recombinant IL-2 has the same effects as naturally occurring IL-2. Recombinant technology provides large amounts of IL-2, which permits cancer researchers to treat patients with cancer.

This is known as immunotherapy or biologic therapy.

How you will receive interleukin-2

You will receive subcutaneous (under the skin) injections of IL-2. These injections will be given through a needle in the upper arm, thigh, hip, or belly. The dose and schedule of injection will be determined by your protocol.

The injections during the first week of therapy will be given in the hospital. The first day your nurse will give you the injection and show you the steps to mix, draw up, and give the injection. Over the next few days you will learn to give yourself the injection by watching a movie, reviewing the steps with your nurse, and using the medical supplies you will need at home.

Then, the nurses will help you do a subcutaneous injection on your own. They will ask you to demonstrate it back to them to make sure you are comfortable with it. You will inject yourself

**Underlined words are defined in the Glossary.*

before you leave the hospital and when you are back at home.

Your health care team will give you a sheet of paper showing how much IL-2 to give yourself at home. IL-2 comes in powder form and must be refrigerated. It must be mixed (reconstituted) with sterile water.

Throughout your course of immunotherapy, your health care team will check how you tolerate your treatment. We will ask you to keep a diary of side effects common to patients who receive IL-2.

Discharge instructions

Food

As soon as you are comfortable giving yourself IL-2 injections, you will return home. You will have an appointment for follow-up visits to the Clinical Center

Please observe the following while you are home:

- Take fluids as tolerated. Concentrate on high calorie fluids such as instant breakfasts and milk shakes.
- If you lose your appetite, gradually increase food intake. Bland starches such as rice, noodles, and mashed potatoes are well tolerated. Try small, frequent meals. As your appetite returns, add high protein foods, such as meat, eggs, milk, and cheese.
- Use oils, creams, and lotions as needed. Use a mild soap, such as Basis. Aveeno baths may decrease itchiness. Skin changes may continue for several weeks near injection sites.

Skin care

- Use a strong sunblock (SPF 15 or greater) if you are out in the sun longer than a few minutes. Remember to reapply sunblock if you are sweating a lot or if you are out for a long time. Protect yourself from the direct rays of the sun. Wear loose-fitting cotton clothing and a hat.

Activity

- Do not operate machinery or drive a car while taking medications that cause drowsiness.
- Maintain your activity level. Plan for rest periods. Know that fatigue is an expected side effect of your therapy.

Medical problems

- Maintain contact with your local doctor
- In case of emergency, first call your local doctor. After you have spoken with your local doctor, call your immunotherapy doctor
- *Always carry your medical advisory card.* Show this to all your other doctors and emergency room staff.

Blood tests at home

You will need to have your blood drawn for certain blood tests while you are home. Apheresis nurses at the Clinical Center will contact your lab at home to help make the arrangements. The following blood tests will be needed:

- complete blood cell count and differential
- blood urea nitrogen, creatinine

- SGOT, SGPT, alkaline phosphatase, total bilirubin
- creatinine phosphokinase
- PT and PTT.

Important Note

Check with your NIH doctor before taking **any** prescription drugs ordered by another doctor.

Check with your immunotherapy team before using **any** medications you buy over the counter, including eye drops, ear drops, and nasal sprays.

Do not use medications containing steroids or cortisone. They prevent IL-2 from working. Many over the counter skin products for poison ivy, psoriasis, and insect bites contain steroids or cortisone. **Read all labels carefully.**

You may have altered sleep patterns or unusual dreams. These will clear up after treatment.

You may have mood swings and occasional tearfulness for a while.

Giving a subcutaneous injection

General information

1. You will be giving yourself injections of IL-2.
2. The injections should be given at about the same time each day.
3. Store the IL-2 in the refrigerator but not the freezer. Remove the vial from the refrigerator 30 minutes before administration so it can reach room temperature. **DO NOT** shake the vial when mixing.
4. Collect the necessary supplies for administration. This includes the medication, sterile saline or sterile water, sterile disposable needle and syringe, alcohol pads, and puncture-proof disposal container. The container can be a coffee can or leak-proof, reclosable milk jug.
5. Wash your hands well and take any premedication.

Preparing IL-2

1. Prepare the medication according to the instructions on the worksheet. After removing the cap from the vial, be sure to wipe the top of the vial with an alcohol pad.
2. Use only the syringes and needles given to you by your healthcare team. **Do not reuse syringes and needles.**
3. Pull back on the plunger of the syringe to allow air to enter. The amount of air should equal your dose of medication.
4. Carefully remove the needle cap.

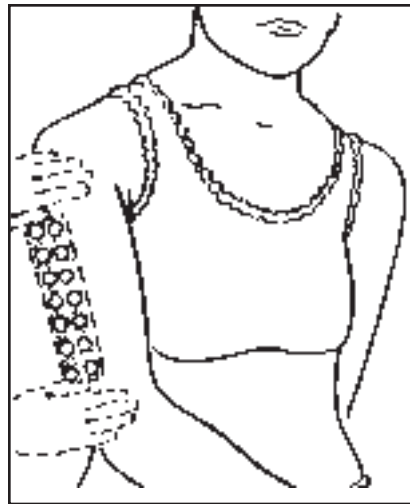
5. Place the needle through the rubber stopper on the vial and push the plunger down so that all the air goes into the vial.
6. Turn the vial and syringe upside down. Draw back the plunger until the syringe is filled with the correct dose of medication.
7. If air bubbles are present, tap the syringe so that the air floats to the top, then push the air up into the vial.
8. Remeasure until the correct dose of medication is in the syringe.
9. Remove the needle from the vial.

Giving yourself the injection

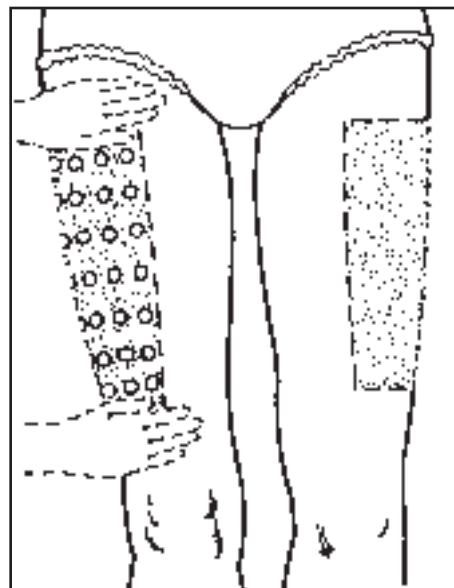
1. Select the site for injection.

The best place for injection has a layer of fat between skin and muscle. This is called the subcutaneous layer and includes these parts of the body:

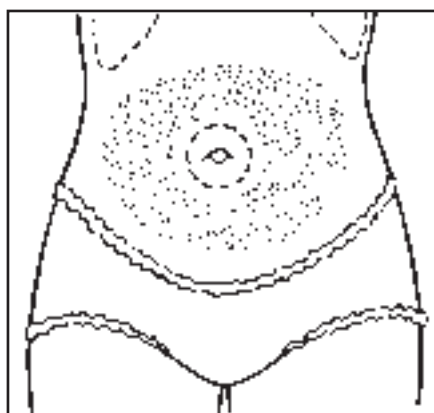
- outer surface of the upper arm
- top of thighs
- abdomen, except the navel or waistline.



Injection sites on the arm.



Injection sites on the thigh.



Injection sites on the abdomen.

If you are exceptionally thin, use only the thigh or outer surface of the arm as injection sites.

2. *Do not inject medication repeatedly into the same site.*
3. Rotate your injection sites in a regular pattern.
4. Cleanse the injection site with a fresh alcohol pad.
5. Wait for the site to dry.
6. Remove the needle cap.
7. Pinch a 2-inch fold of skin between your thumb and index finger.
8. Hold the syringe the way you would a pencil. Insert the needle at a 45 to 90 degree angle to the pinched-up skin.
9. Insert the needle into the skin fold. If you do this quickly, you will feel very little discomfort.
10. Hold the syringe with one hand. With the other, pull back the plunger to check for blood. If you see blood in the solution in the syringe, **do not inject.**

Withdraw the needle and start again at a new site.
11. *If you do not see blood,* slowly push the plunger to inject the medication. Press the plunger all the way down.

12. Remove the needle from the skin and gently hold an alcohol pad on the injection site. Do not massage or apply heat to the site.

13. If there is bleeding, apply a bandage.

14. Immediately put the syringe and needle into the disposal container. It is not necessary to recap the needle.

Side effects of subcutaneous IL-2

Many patients say the side effects of immunotherapy make them feel like they have the flu. These symptoms are common and include the following:

- fever, chills, or muscle aches
- fatigue or tiredness
- nausea, vomiting or loss of appetite, diarrhea
- rash, redness, peeling, swelling and/or pain at the injection site
- weight gain caused by swelling
- reddened, sore mouth, dry lips.

Which side effects should I alert my doctor about?

Other side effects you may experience to some degree are these:

- restlessness, anxiety
- forgetfulness
- decreased need to urinate.

Important Note

You **must** notify your health care team about the following side effects:

- confusion
- dizziness
- shortness of breath
- painful or burning urination
- chest pain
- persistent fever greater than 102° F after taking Tylenol
- severe diarrhea that does not respond to medication after 1 day
- vomiting that does not respond to medication and limits what you are able to eat, lasting more than 1 day
- blood in the urine or stool
- unusual bruising or bleeding
- no urine made in 24 hours
- swelling or rapid weight gain.

If you have any of these side effects, call the numbers in the Resource List any time of day or night.

You will probably be taking other medications during treatment to help you manage the side effects of immunotherapy. For example, you must take acetaminophen (Tylenol) 650 mg by mouth (or rectally, if nauseated) every 4 to 8 hours. Acetaminophen helps ease the fever, aches, and joint stiffness you may feel.

Caution: Do not take more than four (4) grams of acetaminophen a day.

The chart on the next page lists medications that may also be given to you during your therapy.

Skin care during treatment

Many patients develop some type of skin reaction during IL-2 therapy. The reaction can range from dry, reddened skin with mild itching, to flaking or peeling skin. Dry, peeling skin, which may last for several weeks, can occur anywhere on your body.

Some helpful lotions are Lubriderm, Eucerin, Aloe Vera and Aveeno. Using these oils, creams, and lotions may help relieve the symptoms. Some patients find it helpful to use them at the start of therapy. Aveeno baths may also provide some relief. Aveeno contains oatmeal to ease itchiness. Use a mild soap such as Dove, Purpose, or Basis for bathing.

You may have skin changes for several weeks near the injection sites. Some patients have rashes and dry skin for several weeks or even months after treatment. It is important to continue careful skin care until all dryness has disappeared.

Because your skin is so sensitive, you must protect yourself from direct sun rays by using a sun block of SPF 15 or greater with both UVA and UVB protection. It is important to apply sun block even on cloudy days since the UVA and UVB rays go through clouds. Remember to reapply sun block if you are sweating or swimming. Be sure to wear a hat and loose-fitting cotton clothes.

Other Medications You May Need During Treatment

| Medication | How given | How Often | Why given |
|---|--|--|---|
| indomethacin (Indocin) | by mouth, or rectally, if nauseated | every 6 hours | decreases aches, fever, and flu-like symptoms |
| ranitidine (Zantac) | by mouth | once or twice a day | decreases stomach acid |
| diphenoxylate hydrochloride and atropine sulfate (Lomotil) | by mouth | after loose stools or every 4 hours | decreases diarrhea |
| loperamide (Imodium) | by mouth | after loose stools or every 4 hours | decreases diarrhea |
| prochlorperazine (Compazine) | rectally or by mouth | as needed or every 4 hours | decreases nausea |
| ondansetron (Zofran) | by mouth | every 8 hours | decreases nausea |
| lorazepam (Ativan) | by mouth | every 6 hours | decreases nausea, anxiety |
| diphenhydramine (Benadryl) | by mouth | every 4 hours | decreases itching |
| Maalox, Mylanta, or Tums | by mouth | as needed | decreases stomach acid/irritation |
| Oatmeal powder/baths (Aveeno) | put in your bath water | as needed | decreases itching |
| hydroxyzine (Atarax) | by mouth | every 4 to 6 hours | decreases itching |

Tiredness and mental changes

Your immunotherapy may cause you to feel very tired or sleepy. This is a common side effect. Although you may feel like sleeping all day, it is important to combine periods of activity with periods of rest. In addition to tiredness, you may feel sad or depressed during treatment. Balanced rest and activity may help to control these feelings. Based on your energy level, you may wish to continue your usual activities including exercise, work, and sexual activity.

Some of the medications you take to help ease the side effects of therapy may also make you drowsy. Two of these drugs are Ativan and Benadryl. If you are taking them, do not operate machinery or drive a car.

Some patients report having disturbed sleep patterns, vivid dreams, and mood shifts. Family members and friends can provide a lot of support at this time. Included in the Resource List at the end of this information is the name of a health care team member who may be of help to you. Do not hesitate to call with any concerns.

Important Note

If you feel confused, or if your family members notice a change in your thinking, notify your health care team immediately.

Nutrition

Immunotherapy may cause problems like nausea or a decrease in your appetite. It is important that you continue eating healthful foods throughout your therapy. Good nutrition helps prevent weight loss. *Remember to drink plenty of fluids (at least 8 to 12 glasses a day) throughout your immunotherapy.*

Immunotherapy may cause you to have a dry, sore mouth. It can also change your sense of taste or decrease your appetite. You may find it easier to eat small, frequent meals instead of three big meals a day. This section lists suggestions on how to cope with various nutritional needs during immunotherapy. If you still have questions, your health care team will arrange a meeting between you and a dietitian, who will offer more advice.

What if I am too tired to eat properly?

- Let someone else do the cooking.
- Let friends and relatives know that delivery of your favorite dishes would be appreciated.
- Before treatment begins, prepare batches of your favorite foods and freeze them in individual servings.
- Stock up on your favorite frozen entrees and dinners that could be heated in the microwave.
- To cut down on cleaning time, cook and serve food in the same container.

- Order dinner out at your favorite restaurant, and be sure to order enough so you will have leftovers for another meal.

What if I am just not hungry?

- Eat small meals more often.
- Keep snacks handy for nibbling.
- Try sipping on fortified beverages or supplements throughout the day. Sometimes it is easier to drink than eat.

What helps when I feel nauseated?

- Eat smaller portions and choose foods that are low in fat. (They are easier to digest and move through the stomach faster.)
- Try lightly salted foods and avoid very sweet foods.
- It may be helpful to rest after eating. Resting should be done sitting up, with your head at least 1 foot higher than your feet. Do not lie down flat for at least 2 hours after eating.
- Ask your doctor to prescribe anti-nausea medication. If you are already taking one kind that does not seem to be working, let your doctor know. There are several choices.
- If the smell of food nauseates you, try cold, odorless foods.
- Stay away from the food preparation area.

What if my taste for some foods has changed?

- Try sucking on hard candies such as peppermints or lemon drops.

- Try drinking liquids such as water, herb tea, ginger ale, fruit juice mixed with club soda, or tomato juice.

- Avoid foods with a strong smell or taste.
- Marinate beef, chicken or fish in wine, soy sauce, or Worcestershire sauce.

What if I have diarrhea?

- Eat smaller amounts of food more often.
- Avoid food that can cause gas or cramps such as carbonated beverages (unless flat), beans, cabbage, broccoli, cauliflower, highly-spiced foods, and chewing gum.
- Try to drink plenty of fluids, especially nonacidic juices, Kool Aid, broth, and Gatorade.
- Limit foods that are high in fiber such as whole grain breads and cereals, fresh fruits and vegetables, nuts, and beans.
- Limit greasy and high-fat foods.

What if I have a dry or sore mouth?

- Eat foods that are moist or liquid.
- Take small sips of liquids between bites of food at mealtimes.
- Eat soft, cold foods such as canned fruits, ice cream, Popsicles, gelatin, pudding, yogurt, melon, cottage cheese, or custard (avoid grains, raw fruits, and vegetables).
- Try high-calorie and high-protein soups and beverages that are easier to swallow (milk shakes, commercial supplements such as Ensure, Sustacal, cream soups, and instant breakfast drinks).

- Try using a straw for beverages and soups for more comfortable swallowing.
- Foods at room temperature or cold foods may be easier to eat. Eat small frequent meals.
- Make foods easier to swallow. Cut food into small pieces, use gravies or cream, margarine, or broth to moisten foods. Stews and casseroles are often easier to swallow.
- Cold food consumed at the beginning of the meal may have a numbing effect, making swallowing other foods easier.
- Mouth rinses of sodium bicarbonate in salt water or chlorhexidine gluconate after meals and when needed may help ease soreness.
- Avoid the following:
 - salty or spicy foods which may hurt your mouth or throat (such as potato chips, salted nuts, chili powder, or chili peppers).
 - acidic foods such as tomatoes, tomato juice or soup, and citrus fruits. Try apricot and pear nectar instead.
 - cigarettes and alcohol.

Eating high calorie and high protein foods

Since you may have a poor appetite and become full more quickly or may not be able to eat large amounts of food, it is important that the food you do eat be power-packed with protein and calories.

When your appetite is poor, every calorie counts. This is a time to use full fat and regular versions of food. Avoid “diet” foods, reduced

fat, and fat-free foods when you are struggling to consume enough calories.

You may wish to include these foods in your diet:

- casseroles
- commercial nutritional supplements
- cream soups
- fruit smoothies
- macaroni and cheese
- milk shakes.

You will find more suggestions on the next pages. A free copy of the book, *Eating Hints for Cancer Patients*, can be obtained at the Clinical Center. This book includes recipes and has an extensive list of foods you may prefer. It is a publication of the National Institutes of Health, National Cancer Institute.

Ways to increase calories and protein

- *Beans (legumes)*
Dry peas, beans, and bean curd (tofu) can be cooked and made into soup or added to casseroles, pastas, and grain dishes which also contain cheese or meat; mash with cheese and milk.
- *Cheese*
Melt on sandwiches, hamburgers, hot dogs, other meats or fish, vegetables, eggs, desserts like stewed fruit or pies; grate and add to sauces, casseroles, vegetable dishes, mashed potatoes, rice, noodles, bread, muffins.

- *Cottage cheese*
Mix with or use to stuff fruits or vegetables; add to casseroles or egg dishes such as quiche, scrambled eggs, souffles; add to spaghetti or noodles; use in gelatin, pudding-type desserts, or cheese cake; add to pancake batter; stuff crepes and pasta-like shells or manicotti.
- *Cream cheese*
Spread on sandwiches, fruit slices, and crackers; add to eggs or vegetables; roll into balls and coat with chopped walnuts, wheat germ, or granola.
- *Egg*
Add chopped, hard cooked eggs to salads and dressing, vegetables, casseroles, creamed meats; beat eggs into mashed potatoes or vegetable purees; add an extra egg to French toast and pancake batter.
- *Egg yolk*
Beat into sauces; add extra yolks to quiche, scrambled eggs, custards, puddings, pancake and French toast batter; a rich boiled custard made with egg yolks, high protein milk and sugar is a good source of calories and protein; add extra hard cooked yolks to deviled egg filling and sandwich spreads.
- *High protein milk*
Blend whole milk with dry milk powder using one cup dry powder to each quart of milk; substitute for regular milk in beverages and in cooking whenever possible; substitute for water in soups, cocoa, and pudding mixes; use on cereals and stewed fruits.
- *Ice cream*
Use in beverages such as sodas, milk shakes or other milk drinks; add to cereals, fruits, gelatin desserts, and pies; blend or whip with bananas and soft or cooked fruits; sandwich between cake slices, cookies, or graham crackers.
- *Meat or fish*
Add small pieces of any cooked meats or fish to vegetables, salads, casseroles, soups, and biscuit ingredients; use in omelets, souffles, quiche, sandwich fillings, chicken and turkey stuffings; wrap in pie crust as a turnover.
- *Milk or cream*
Add to water used in cooking or use in place of water in prepared foods such as hot cereal or soups; serve cream sauces with vegetables and other appropriate dishes.
- *Nuts*
Serve as snacks; add chopped or ground nuts to ice cream, yogurt, puddings, breads, muffins, pancakes, waffles, cookies, meat loaf and hamburgers, vegetable dishes, salads, and sandwiches; blend with parsley or spinach, herbs and cream for a noodle, pasta or vegetable sauce; roll a banana in chopped nuts.
- *Peanut butter*
Spread on sandwiches, toast, muffins, crackers, waffles, pancakes, fruit slices; use as a dip for raw vegetables like carrots, cauliflower, celery; add to meat loaf; flavor soups and sauces, cookies, breads, muffins;

blend with milk drinks and beverages; swirl through soft ice cream and yogurt; top cookies and cake.

- *Plain or sweet yogurt*
Add to fruits and desserts; use to top cereals, pancakes.
- *Powdered milk*
Add to regular milk and milk drinks such as eggnog and milk shakes; use in casseroles, add to meat loaf, breads, muffins, sauces, cream soups, pudding, custards and milk-based gelatin salads or desserts.
- *Textured vegetable protein*
Add to hamburgers, meat loaf, meatballs, spaghetti sauce, ground or chopped meat dishes, casseroles, sandwich fillings.
- *Wheat germ*
Add to casseroles, meat, bread, muffin and pancake or waffle recipes; sprinkle on fruit, cereal, ice cream or yogurt; sprinkle on top of vegetables and toast to add a crunchy topping; use in place of bread crumbs.

Glossary

Immune response—The body's first reaction to an invasion by viruses, bacteria, or other foreign materials.

Immune system—The system of the body that protects it from invasion by foreign substances.

Immunotherapy—Cancer treatment that acts by delivering natural biologic substances to boost, direct, or restore normal immune defenses.

Interleukin-2 (IL-2, rIL-2)—A substance produced by the body's lymphocytes or white blood cells. This substance helps stimulate the growth of white blood cells, which helps to fight infection and cancer. It is one of the biologic agents used in immunotherapy treatment.

Intravenous (I.V.)—Through the vein. An intravenous (I.V.) infusion is given through a needle that is inserted into a vein.

Lymphocyte—Small white blood cells produced by the organs of the immune system. They are essential to fighting foreign invaders in the body.

Recombinant—A process of altering the genes of bacteria so that the bacteria make large amounts of a desired substance.

Subcutaneous (SQ, subQ)—The fatty tissue directly under the skin. A subcutaneous injection is given under the skin into the fatty tissue.

Helpful resources

- National Cancer Institute. (1994). Eating hints for cancer patients (NIH Publication No. 94-2079). Washington DC: U. S. Department of Health and Human Services.
- National Cancer Institute & National Institute of Allergy and Infectious Diseases. (1993). Understanding the immune system (NIH Publication No. 93-529). Washington DC: U. S. Department of Health and Human Services.

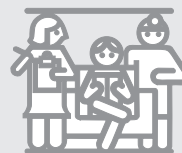
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- National Kidney Cancer Association. (1995). Interleukin-2 therapy: What you should know (Brochure). Sharp, EJ: Editor.
- Rieger, P. T. (Ed.). (1995). Biotherapy: A comprehensive overview. Boston: Jones and Bartlett.
- Schwartzentruber, D. J. (1995). Biologic therapy with interleukin-2: Clinical applications. Principles of administration and management of side effects. In V. T. DeVita, Jr., S. Hellman, & S. A. Rosenberg (eds.), *Biologic therapy of cancer* (pp. 235-249). Philadelphia: JB Lippincott.

How to reach your health care team

During weekdays between 8 a.m. to 4 p.m., call the immunotherapy research nurses first at 301-496-0997.

After 4 p.m. Monday through Friday; Saturday, Sunday, and holidays, call the 2 East Nurses' station: 301-496-3191.

The nurses on 2 East will address your questions or concerns. Please note the name of the nurse you speak with. If the 2 East nurses are unable to help you, they will page the immunotherapy doctor on call (301-496-0997).



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This information is prepared specifically for patients participating in clinical research at the Warren Grant Magnuson Clinical Center at the National Institutes of Health and is not necessarily applicable to individuals who are patients elsewhere. If you have questions about the information presented here, talk to a member of your healthcare team.

Where applicable, brand names of commercial products are provided only as illustrative examples of acceptable products, and do not imply endorsement by NIH; nor does the fact that a particular brand name product is not identified imply that such product is unsatisfactory.

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